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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,024	12/11/2003	David B. Weiner	UPVG0005-101	2356

34132 7590 02/16/2006
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EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT PAPER NUMBER

1648

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,024	WEINER ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-5 and 14-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 14-28 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Office acknowledges the receipt of Applicant's election and amendment filed on 30 January 2006.

Election/Restrictions

Applicant elects Group I, claims 1-5, with traverse. The traversal is on the grounds that there would be no undue burden on the Office in examining the Groups I and II together. Applicant's traversal has been fully considered and is persuasive. Therefore, Groups I and II have been rejoined.

Claims 6-13 have been canceled. Applicants erred in stating "add new claims 14-26" because claims 14-28 have been newly added. Applicant timely traversed the restriction requirement in the reply filed on 30 January 2006. Claims 1-5 and 14-28 are examined in the instant application.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed 15 March 2004, is attached to the instant Office action.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 14-28 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for inhibiting proliferation or preventing activation of T cells with full length Vpr protein, does not reasonably provide enablement for inhibiting proliferation or preventing activation of T cells with a fragment of Vpr protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would

not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The nature of the instant invention is the method of inhibiting proliferation of cells which comprises: the step of contacting cells with an amount of Vpr protein or a functional fragment thereof effective to inhibit cell proliferation; or introducing into cells a nucleic acid molecule that comprises a nucleotide sequence that encodes Vpr protein or a functional fragment thereof that is expressed by said cells. The breadth of the instant claims encompasses inhibiting proliferation or preventing activation of lymphocytes - T cells, B cells, and monocytes - with a fragment of Vpr protein.

The specification nowhere teaches the claimed method. Rather, the specification is a literature review about the interaction of Vpr protein and Vpr fragments with rip-1, a member of the glucocorticoid receptor (GR) type II family, which is not related to the instant invention. The only amount of direction is the disclosure in the prior art. However, the prior art teaches that only full length Vpr can arrest cell growth, while a truncated *vpr* gene expressing a 45 amino acid fragment of Vpr cannot (Rogel, 1995). Therefore, the teaching from the prior art negates the limitation of "a functional fragment thereof" in the instant claims.

Considering the lack of data and working examples in the specification, the broad scope of the claims, the complex state and nature of the art, and the negative teachings regarding unpredictability in this art, one skilled in the art would have to engage in an undue amount of experimentation to practice the invention as claimed.

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"Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970). In the instant case, a method of inhibiting proliferation or preventing activation of lymphocyte/cells is not considered routine in the art and, without sufficient guidance, the experimentation left to those skilled in the art is undue or unreasonable under the circumstances. It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQZd 1714 (BPAI 1991).

The instant invention, based on the evidence as a whole, in light of the factors articulated by the court in *In re Wands*, lacks an enabling disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5 and 14-28 are rejected under 35 U.S.C. §102(a) as being anticipated by Rogel *et al.* (February, 1995, as filed in IDS).

Instant claims are directed to a method of inhibiting proliferation of cells which comprises: the step of contacting cells with an amount of Vpr protein or a functional fragment thereof effective to inhibit cell proliferation; or introducing into cells a nucleic acid molecule that comprises a nucleotide sequence that encodes Vpr protein or a functional fragment thereof that is expressed by said cells.

Rogel *et al.* teach that transfection of two T cell lines, Sup T1 and MT4 cells, with viral strains containing Vpr protein, which is essentially contacting cells with Vpr protein, prevents T cell proliferation or activation (page 883, Figure 1). Rogel *et al.* demonstrate similar results in peripheral blood mononuclear cells (PBMCs), which are, by definition, lymphocytes and monocytes in peripheral blood. Rogel *et al.* subsequently teach that transfections with plasmids that express Vpr alone indicate that Vpr expression can alter the progression of cells in the cell cycle and therefore may mediate its effect through prevention of cell proliferation (page 886 and Discussion).

Thus, the instant invention is anticipated by Rogel *et al.*

Remarks

No claim is allowable.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D., whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902.

Louise Humphrey, Ph.D.
Patent Examiner
08 February 2006


JEFFREY STUCKER
PRIMARY EXAMINER